EXHIBIT 1

UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF COLUMBIA

COLLAGENEX PHARMACEUTICALS, INC., Plaintiff, v. TOMMY G. THOMPSON, DEPARTMENT OF HEALTH AND HUMAN SERVICES, MARK B. MCCLELLAN, and FOOD AND DRUG ADMINISTRATION, Defendants.	CIVIL ACTION NO. 03-1405 (RMC)

DECLARATION OF BRIAN M. GALLAGHER, PH.D.

I, BRIAN M. GALLAGHER, PH.D., declare as follows:

1. I am the Chairman, President and Chief Executive Officer of CollaGenex Pharmaceuticals, Inc. ("CollaGenex"). As Chairman, President and Chief Executive Officer, I oversee the activities of CollaGenex including the commercial and scientific development of its products. I am familiar with the marketing of drug products in general, with the marketing and prospects for CollaGenex's product Periostat® (doxycycline hyclate 20 mg), and with the FDA regulatory process. This declaration is based upon my personal knowledge and the records maintained by CollaGenex in the course of its regular business activity.

2. I have a Bachelor of Science degree from St. Louis University and a Doctor of Philosophy from St. Johns University. I joined CollaGenex in April 1994 as President and Chief Executive Officer and was elected to the Board of Directors in November 1994. From 1988 until

I joined CollaGenex, I was employed by Bristol-Myers Squibb Company and its predecessor, Squibb Corporation, in various executive positions, including strategic planning, worldwide product and business development and marketing. I was President of Squibb Diagnostics, the in vivo imaging pharmaceutical division where I was responsible for drug development, including submitting New Drug Applications to the Food and Drug Administration ("FDA") and other regulatory authorities worldwide. Prior to that, I served for ten years with E.I. DuPont de Nemours & Co. in a variety of pharmaceutical research, development, marketing, and business management positions.

CollaGenex and Periostat

3. CollaGenex is a corporation organized under the laws of the state of Delaware and having its principal place of business and corporate offices at 41 University Drive, Newtown, Pennsylvania.

4. CollaGenex is a small pharmaceutical company focusing on providing innovative therapies to treat unmet medical needs, primarily in the dental and dermatological markets. Its flagship and primary product is Periostat. It employs approximately 150 people.

5. CollaGenex was formed as a private company in 1992 for the purpose of developing a new technology discovered at the State University of New York at ("SUNY") Stony Brook. Researchers at SUNY had discovered that tetracyclines possess properties, independent of their antimicrobial properties, which are useful in the treatment of inflammatory diseases and diseases that result in bone deficiencies. These properties include the ability to reduce the activity of tissue destruction enzymes, such as collagenase, which are responsible for pathological tissue destruction and the ability to stimulate new bone protein synthesis. Tissue destruction enzymes are implicated in periodontitis, in acne, in rosacea, and possibly in other

diseases. CollaGenex is conducting clinical studies to evaluate whether doxycycline hyclate, a derivative of tetracycline, is effective in treating acne and rosacea, and has already demonstrated its utility in treating periodontitis.

6. Adult periodontitis is a chronic disease characterized by the progressive loss of attachment between the tooth and the surrounding alveolar bone, ultimately resulting in tooth loss. In patients with adult periodontis, enzymes including collagenase become overactive and destroy periodontal support tissues such as the ligaments that attach teeth to the bone in the jaw. The breakdown of the connective tissues that make up the supporting structures of the tooth results in bone loss, loosening of the tooth, and ultimately tooth loss.

7. Periostat is a systemic, orally administered, prescription drug consisting of a 20 mg. dose of doxycycline hyclate that helps treat periodontitis. Periostat works as a collagenase inhibitor. The suppression of collagenase helps prevent further destruction of the periodontal support tissues and allows the body's natural repair mechanisms to promote a reattachment of teeth.

8. Non-surgical treatment for periodontitis often includes scaling and root planing, a procedure involving scraping the surface of the tooth above and below the gum line to remove plaque and calculus from the tooth surface and to smooth the tooth root. If these non-surgical treatments do not achieve periodontal health, periodontal surgery may be required.

9. As an adjunct to scaling and root planing, Periostat has been clinically shown, and approved by FDA, to improve attachment of the tooth to the gum and reduce the depth of periodontal pockets that form when attachment is lost in patients with adult periodontitis. Periostat is the first drug to be approved by FDA to treat adult periodontitis by inhibiting enzymes and the first approved drug to use doxycycline hyclate to inhibit enzymes.

The NDA Approval Process

10. Before a new drug may be marketed in the United States, it must be approved by the FDA. To obtain approval, a sponsor of a pioneer drug like Periostat must submit a new drug application ("NDA"). An NDA must include full reports of investigations to show whether or not the drug is safe and effective for use as well as information about the manufacture, processing and packing of the drug. Developing the necessary information and data is a lengthy and costly enterprise, involving significant expenditures of money and many peoples' time and effort.

11. At the core of an NDA are clinical studies demonstrating that the drug is safe and effective for its proposed use. Clinical studies, particularly studies designed to support FDA approval, are expensive and time-consuming. Protocols must be developed, including multiple forms for collecting data; investigators to conduct the studies must be recruited and compensated; institutional review board approvals must be obtained; drug and placebos must be manufactured; subjects must be recruited, compensated, treated and evaluated in numerous visits; data must be collected and analyzed by biostatisticians; and a voluminous report must be written.

12. In 1992, CollaGenex met with FDA on the design of the clinical studies. It then conducted three clinical studies to evaluate Periostat's safety and effectiveness, at a cost of over $6 million. In addition, CollaGenex conducted clinical pharmacokinetic studies to learn how Periostat functions in the human body.

13. Once CollaGenex had developed the information to support an NDA, it had to prepare the NDA for FDA review. That process began with a pre-NDA meeting with FDA held on May 15, 1995. At that meeting, CollaGenex learned for the first time that FDA had concerns about the design of its studies, which, by that time, were nearly complete. At the same meeting,

FDA asked CollaGenex to conduct a number of expensive animal toxicity studies focused on demonstrating that Periostat has no deleterious effect on the reproductive system, that it is not a carcinogen, and that it has no effect on the genes.

14. Following the meeting, CollaGenex designed and conducted an additional study using the revised study design that FDA was now advocating, at an additional cost of over $3 million. It also conducted nine toxicity studies to satisfy FDA's concerns.

15. CollaGenex submitted a 129 volume NDA for Periostat on August 30, 1996. In August 1997, a year after the NDA was submitted, FDA notified CollaGenex that the application was not approvable, primarily because FDA did not believe that the three primary clinical studies included in the NDA provided a sufficient demonstration of effectiveness. CollaGenex met with FDA the following November to try to resolve the differences of opinion. In December 1997, FDA notified CollaGenex that the NDA was still not approvable. In March 1998, CollaGenex met again with FDA to discuss adding data from the new clinical study, and submitted those results shortly thereafter.

16. FDA finally approved Periostat in September 1998, twelve years after the clinical studies began and two years after the NDA was originally submitted. As part of the Periostat approval, FDA required CollaGenex to conduct still more studies, which were to be completed after the approval. These included a two year carcinogenicity study in rats, a one year toxicity study in monkeys, and a food versus pharmacokinetic fasting study in humans, studies which have been completed and reported to FDA at a cost of over $2.5 million.

17. CollaGenex invested approximately $22 million and the time and effort of numerous scientists, clinicians, manufacturing experts, regulatory affairs experts, lawyers, and others in the risky but ultimately successful effort to obtain FDA approval.

Marketing

18. Like any drug company planning to launch a new drug, CollaGenex began to explore the market for Periostat prior to receiving FDA approval. During the months preceding the launch of Periostat, CollaGenex undertook extensive market research to determine how best to introduce Periostat. Market researchers conducted numerous one-on-one interviews with dentists and periodontists to determine how patients were being treated, the state of the art in management therapies for patients, the perceived gaps in treatment and the needs of practitioners and patients. This market research was essential in making decisions about pricing and distribution and in developing strategies to effectively market Periostat.

19. Because Periostat was not only new to the market but also an entirely new category of drug, the marketing obstacles were especially great. A company seeking to introduce a new antihypertensive drug, for example, does not need to educate the medical profession about the treatment benefits of antihypertensives; these are already known by the medical community and patients. Until Periostat, there were no pharmaceuticals to treat periodontitis which utilized enzyme suppression as a mechanism of action.

20. Because CollaGenex, Periostat, and the concept of a systemic anti-collagenase pharmaceutical product to treat periodontitis were all new to dentists, periodontists and other dental professionals, no market existed for Periostat. Over the course of the five years following FDA approval, CollaGenex has conducted extensive market research and used a variety of techniques to develop such a market.

21. When FDA approved Periostat in November 1998, CollaGenex had a small number of sales representatives ready to begin marketing. Following approval, CollaGenex

immediately recruited and trained additional representatives. By January 1999, CollaGenex had a sales force of 100 sales representatives divided into eleven districts nationwide.

22. Dentists and periodontists who performed a large number of scaling and root planings in their practices were identified as potential high volume prescribers of Periostat. Each sales representative was assigned a territory that included approximately 200 of these dentists and periodontists, and visited each in six to eight week cycles. CollaGenex designed extensive educational materials, video presentations, detail aids, and product samples for use by the representatives to familiarize dentists, periodontists, and dental professionals such as dental hygienists, with the benefits of the new therapy advantages offered by Periostat. By the end of 1998, the cost of direct selling and marketing efforts for Periostat already exceeded $7 million.

23. Because peer-to-peer communications proved vital to increasing the acceptance of Periostat, CollaGenex arranged speaking engagements and teleconferences where more than 150 Periostat advocates shared their experiences with 10,000 other dentists, periodontists, and other dental professionals. CollaGenex also organized 200 teleconferences, during which over 2,500 dentists, periodontists and other dental professionals listened to presentations and had the opportunity to question respected practitioners with Periostat experience. Short presentations

by sales representatives were also used to deliver the message about the availability and use of Periostat to dentists, periodontists, and other dental professionals.

24. The CollaGenex sales force, consisting primarily of dental professionals and pharmaceutical representatives, received intensive sales training essential to the sales and marketing efforts. New representatives received four weeks of field training and two weeks of intensive office training on topics covering periodontal disease, host response, and pain management, among others. Training continues at district-level meetings throughout the year.

25. Through continuing research into the practices of these dentists and periodontists that prescribed Periostat, CollaGenex discovered that the dental profession is more conservative in its acceptance and adoption of new medical therapies than other medical specialties. This proved especially true for treatments of adult periodontitis, where the standard mechanical therapy, scaling and root planing, had existed for many years.

26. Market research revealed that many dentists were prescribing Periostat only to a subset of their eligible patients, largely their most advanced or refractory patients. CollaGenex then set out to familiarize practioners and patients with the clinical research demonstrating that Periostat improves the treatment outcomes for a broad range of patients with adult peridontitis, and that it significantly slows the progression of this chronic disease, helping to prevent a moderately diseased patient from progressing to a severely diseased patient.

27. By June 2000, CollaGenex launched the Periostat Expanded Use Initiative to promote this early intervention by enhancing dentists, periodontists, and other dental professionals' understanding of the potential uses and benefits of Periostat. The Expanded Use Initiative was designed to highlight the efficacy of Periostat in halting disease progression from

a moderate condition to a severe, possibly debilitating disease. The sales force training and educational materials were all revised to coordinate their efforts with this campaign.

28. While awareness of Periostat and its benefits grew among dentists and periodontists, market research showed that consumer awareness remained low. In response, in the fall of 2000, CollaGenex launched a Direct to Consumer ("DTC") campaign in two test cities, Tampa and St. Louis. The results were promising. The prescription growth rates in the test cities grew at a significantly faster pace than the rest of the country as more consumers and dentists became aware of the existence and benefits of Periostat.

29. Because the research had shown that the DTC campaign was highly effective in raising the awareness of Periostat among patients, dentists, periodontists and other dental professionals, it was expanded to 22 markets. The campaign was supported by television advertising, direct mail, the creation of websites and installation of toll-free numbers that allowed dentists, periodontists, and other dental professionals and consumers to access information about Periostat.

30. The cost to CollaGenex of these efforts was significant. CollaGenex expended over $19.5 million in 1999 in direct sales and marketing expenses, over $20 million in 2000, and over $24 million in each of 2001 and 2002.

31. The expenditures were effective; sales of Periostat increased to $20.5 million in 2000, $30 million in 2001, and $36.5 million in 2002. CollaGenex had to develop the market for Periostat, and did.

Patent Protection, Exclusivity, and the West-ward Application

32. CollaGenex expected to be able to market Periostat for a lengthy period without generic competition under the provisions of the 1984 Hatch Waxman amendments to the Food, Drug, and Cosmetic Act ("Hatch Waxman").

33. Hatch Waxman both authorizes Abbreviated New Drug Applications ("ANDAs"), which provide a shortcut to FDA approval of generic drugs, and provides marketing protection for innovative drugs that might otherwise be copied before the sponsor has had time to reap the rewards of its investment in innovation.

34. ANDAs are used to request FDA approval of generic copies of FDA approved innovative drugs. An ANDA is not required to include full safety and effectiveness testing of the generic drug, but rather relies for proof of safety and effectiveness on a showing that the generic drug is bioequivalent to the innovative drug. Bioequivalence testing is far less expensive and time-consuming than are the clinical studies required to support an NDA.

35. The Hatch Waxman patent protection provisions create a process that allows sponsors to prevent FDA approval of an ANDA while the validity of patents on the innovative drug is being litigated. Under Hatch Waxman, innovative drugs may also qualify for a period of exclusivity – that is, a period during which FDA will refuse to approve ANDAs for generic copies of the drug.

36. CollaGenex properly listed the Periostat patents in its NDA, which should have triggered the Hatch Waxman patent protection process. FDA, however, did not publish them in the Orange Book. Because Periostat is the first approved drug to use doxycycline hyclate 20 mg and, to my knowledge, is the first drug with the active ingredient doxycycline hyclate to have

been submitted under section 505(b) of the Food, Drug, and Cosmetic Act, it should have also been awarded five years of exclusivity.

37. Many antibiotics, however, are not eligible for Hatch Waxman protection. In approving Periostat, FDA wrongly concluded that Periostat is an antibiotic drug and denied Periostat Hatch Waxman exclusivity and patent protection.

38. FDA's decision to deny Hatch Waxman protection to Periostat left the door open for generic manufacturers to submit, and for FDA to review and approve, ANDAs for generic copies of Periostat. Had CollaGenex received the Hatch Waxman protections to which I believe it is entitled, I estimate that FDA would be precluded from approving a generic copy of Periostat until at least April 2004.

39. On or about August 30, 2001, West-ward Pharmaceutical Corporation ("West-ward") submitted an application to FDA to market a generic copy of Periostat. West-ward Citizen Petition, Aug. 13, 2002, Docket 02P-0367, available at http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/082802/8001fdbd.pdf.

40. West-ward develops, manufactures and markets a broad range of prescription and over the counter pharmaceuticals, including analgesics, antibiotics, prescription vitamins, psychotherapeutics, antiepileptics, antihypertensives, cardiovascular products, and bronchial dilators. Hikma Pharmaceuticals website, p. 4, at http://www.hikma.com/plants.html (last visited June 5, 2003).

41. West-ward is a wholly-owned subsidiary of Al Hikma Group, a Jordanian company. Id. at http://www.hikma.com/invest.html (last visited June 5, 2003). Al Hikma is a

private shareholding company that employs over 500 people and exports between 70 and 80 percent of its sales. Karmokolias, The Private Sector and Development: Five Case Studies, available at http://www.ifc.org/publications/pubs/rog/rog2/Jordan (last visited June 5, 2003); Export & Finance Bank, June 13, 2001, p. 3, available at http://www.efbank.com.jo/investment.html (last visited June 5, 2003). On information and belief, Al Hikma is larger than CollaGenex. Al Hikma and West-ward market many more products than does CollaGenex.

42. When CollaGenex learned of West-ward's application, CollaGenex patent counsel wrote to West-ward to advise West-ward of the existence of CollaGenex's patents covering the use of Periostat. Numerous efforts to resolve the patent infringement issues were unsuccessful, and CollaGenex sued West-ward for patent infringement on February 13, 2003. That case is still pending.

43. FDA has not approved the West-ward application, but FDA's review of the application continues. West-ward has stated that FDA approval is imminent.

44. Mutual Pharmaceutical Company ("Mutual"), based in Philadelphia, Pennsylvania, is a national supplier of generic pharmaceuticals and distributes one of the most extensive product lines in the generic industry. See http://urlmutual.com (last visited June 5, 2003).

45. About two weeks ago, CollaGenex learned that Mutual has requested that its generic copy of Periostat be added to the New Jersey formulary. As a rule, companies do not apply to add products to the New Jersey formulary unless the product is approved or thought

by the sponsor to be close to approval by FDA. CollaGenex therefore believes that Mutual has submitted an ANDA to FDA for a generic copy of Periostat.

46. Based on the date of FDA approval of the Periostat dosage form Mutual is copying, the time it would likely take Mutual to obtain CollaGenex product, conduct bioequivalence studies, and prepare an ANDA, and the usual FDA review period, the Mutual ANDA may well be close to approval.

47. Other companies also may have submitted ANDAs for generic copies of Periostat. CollaGenex has no way to determine with any certainty whether other ANDAs for generic copies of Periostat have been submitted to FDA, when they were submitted, or whether they are close to approval.

48. Unless CollaGenex can obtain Hatch Waxman protections, FDA could and, in fact must, approve the West-ward ANDA, if the Mutual ANDA, and any other ANDAs that have been submitted if the application meets the statutory criteria for approval.

Irreparable Harm to CollaGenex

49. FDA's deprivation of CollaGenex's rights under Hatch Waxman and FDA's approval of an ANDA for a generic copy of Periostat would cause immediate and irreparable injury to CollaGenex.

50. CollaGenex depends on the revenues from Periostat for its continued viability. CollaGenex is at a critical point in its development; it is still building the market for Periostat, and it cannot yet finance its research and development program from sources other than Periostat's revenues. CollaGenex needs to be allowed to recoup its investment in Periostat. At this point, every penny of revenue is required to make the company secure, and losing it would irreparably injure CollaGenex.

51. CollaGenex's only significant revenue comes from sales of Periostat. During 1999, 2000, 2001, and 2002 Periostat accounted for approximately 95%, 84%, 87%, and 82%, respectively, of the total revenues of CollaGenex. Since the founding of CollaGenex in 1992, only the last two quarters of 2002 yielded a net positive income for CollaGenex, although CollaGenex still experienced a net loss for 2002.

52. Once a generic drug is introduced in commerce, it quickly gains a large share of the market. During the first full calendar year after the introduction of a generic drug, an innovator drug loses an average of 44 percent of their market. Congressional Budget Office, How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry (July 1998). Generics cost an average of 25 percent less than the original drug at retail prices, reflecting the lower research and development costs and lower costs for FDA approval. A loss of market share anywhere in the range of this magnitude would erode the financial base of CollaGenex, cause extreme hardship and threaten its viability. The approval by FDA of an ANDA and the introduction of generic Periostat into the market would damage CollaGenex beyond a simple diminution in revenue.

53. CollaGenex is a small company that can ill afford to withstand a loss of revenue.

54. CollaGenex has been able to enter and grow in this competitive pharmaceutical market because of its successful development of an innovative product, Periostat, and its ability to develop a market for that drug product. CollaGenex has invested approximately $70,000,000 to develop and introduce Periostat to the marketplace, which it has yet to recoup from sales of Periostat. CollaGenex will continue to incur significant expenses with respect to the sale and marketing of Periostat (or risk even greater loss of revenue if it does not),

continuing clinical development for other indications for Periostat, continuing development of other applications of sub-antimicrobial doses of doxycycline hyclate, and development of other products.

55. If West-ward, Mutual and others obtain ANDAs for generic copies of Periostat, they will be able to free ride on CollaGenex's substantial investment in innovation long before CollaGenex has had an opportunity to recoup its investment.

56. Severely diminishing the revenues from the sales of Periostat would force CollaGenex to dramatically reduce its staff and its marketing efforts. Highly skilled employees, having gained expertise by their work in the technology, would be laid off. CollaGenex employs over 150 people in marketing, manufacturing and research and development, all of whom are responsible for, and reliant on the continued success of Periostat for their employment.

57. Severely diminishing revenues also would force CollaGenex to abandon development work underway to identify new and clinically valuable applications for the technology, including its current work on treating acne and rosacea, and its plans to explore the technology's applications in other uses. Drug companies are evaluated as much on their "pipeline" of new products as on their marketed products. Without a "pipeline," the company would have difficulty recruiting talented staff and convincing investors that CollaGenex has a future.

58. CollaGenex would also become a less attractive candidate for investors as its revenue and product development activities were scaled back. CollaGenex' stock price would drop precipitously and immediately, as the market factored in the anticipated reduction in

revenues and reduced potential for new product development. Current shareholders would suffer losses of many tens of millions of dollars in market value and the company would suffer irreparable damages.

59. CollaGenex currently enjoys a reputation as an up-and-coming company – a reputation earned by many years of hard work, millions of dollars of investment, and the goodwill and recognition acquired as the sole marketer of a breakthrough drug like Periostat. Losing that reputation and recognition as the sole developer and marketer of an innovative drug product based on an innovative technology would severely harm CollaGenex.

60. The impact of a loss of revenues on CollaGenex will be worse than for most other pharmaceutical companies because CollaGenex is small compared to other companies in the industry, and has fewer products. Mutual, for example is a large national supplier of generic pharmaceuticals that holds approvals for over 45 prescription drugs and distributes one of the most extensive product lines in the generic industry. West-ward is a wholly-owned subsidiary of Al Hikma, an international pharmaceutical company with annual sales in 2000 of over $48 million.

61. The kind of injury that CollaGenex would suffer – the loss of its prospects for years if not forever – cannot be compensated financially. Even if it could, CollaGenex would have no way to recoup its losses from the government, which has no financial liability for erroneous decisions in these circumstances.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 6/5/03

BMGallagher

BRIAN M. GALLAGHER, PH.D.